Social Media, Rx Promotion, & FDA

Results of a survey of readers & followers of *Pharma Marketing News*, Pharma Marketing Blog, and @pharmaguy

John Mack

Publisher, *Pharma marketing News* & Pharma Marketing Blog

@pharmaguy on Twitter

johnmack@virsci.com

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John Mack has Been Here, Done This

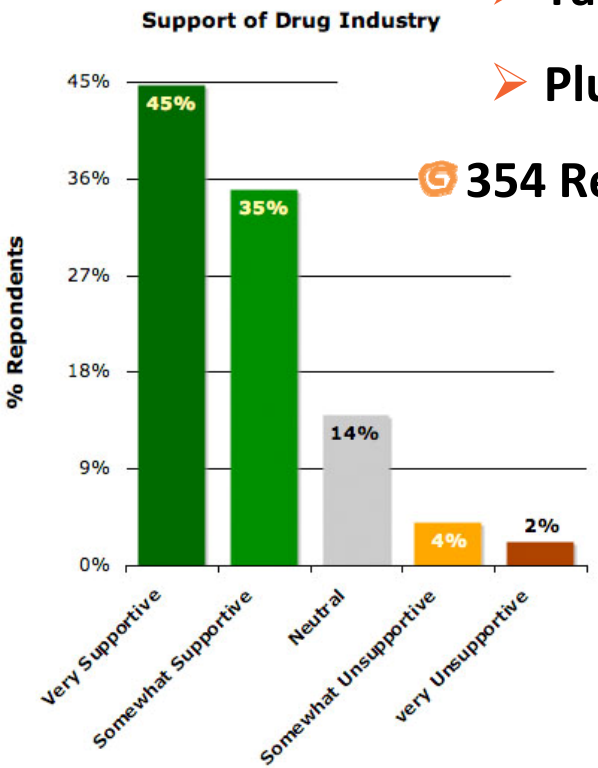
- Testified as Panel Member during 1996 FDA Hearing on Internet
- Co-Founded Internet Healthcare Coalition (1997)
- Co-Authored the eHealth Code of Ethics (2000)
- Blogged about pharmaceutical marketing best & worst practices since 2005
- Creator of "PhRMA Intern" and "FDA Intern" – strange bedfellows or mortal enemies?

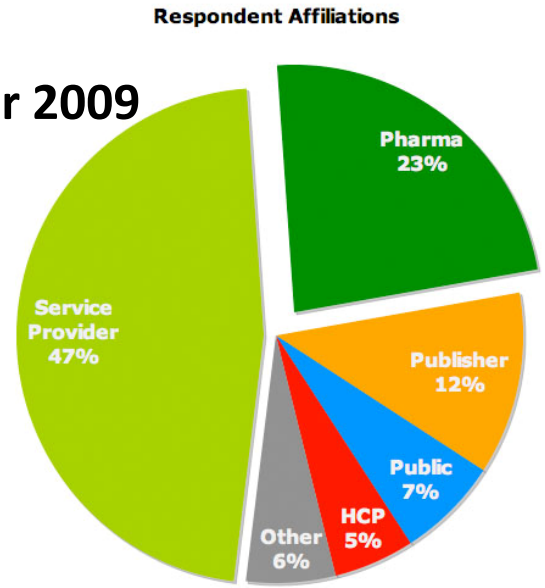
Publications & Social Media Accounts

- **Pharma Marketing News**
  - Monthly electronic newsletter
  - 6,880 opt-in subscribers
  - Eighth consecutive year of publication
  - www.news.pharma-mkting.com
- **Pharma Marketing Blog**
  - 20,000 visits per month
  - pharmamkting.blogspot.com/
- **PharmaGuy Twitter Account**
  - 4,750 Followers
  - Twitter.com/pharmaguy

Survey Overview

- Online — started 20 September 2009
- Includes All 19 questions for which FDA seeks answers
  - Tallies votes on specific answers/solutions
  - Plus 575 comments
- 354 Respondents as of 1 November 2009
  - 126 Blog readers
  - 101 PMN subscribers
  - 64 Twitter followers
  - 45 Web site visitors





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Part 1

- Accountability, Disclosure, Corrections
- Fulfilling Regulatory Requirements with Regard to Fair Balance and Submission for Review
- Posting Corrective Information

Accountability: Best Practices

- **DISCLOSURE of involvement with or influence over 3rd-party social media content should be prominently displayed alongside relevant content when possible.**
  - **Half of survey respondents agree***
- **Each company should have a Public Social Media Policy (SMP) that includes a notice of its transparency/disclosure and other policies relating to social media. [Just like every pharma company has a *public* privacy policy that applies to all its product Web sites, each pharma company should have a public SMP that applies to all its social media activities, whether owned or sponsored by the company.]**
  - **About two-thirds of survey respondents agree***
- **Companies should monitor social media sites for unauthorized use or modification of its approved content and make a best effort to remove or correct the content. But they should only be REQUIRED to do so only for sites owned or directly sponsored by them.**

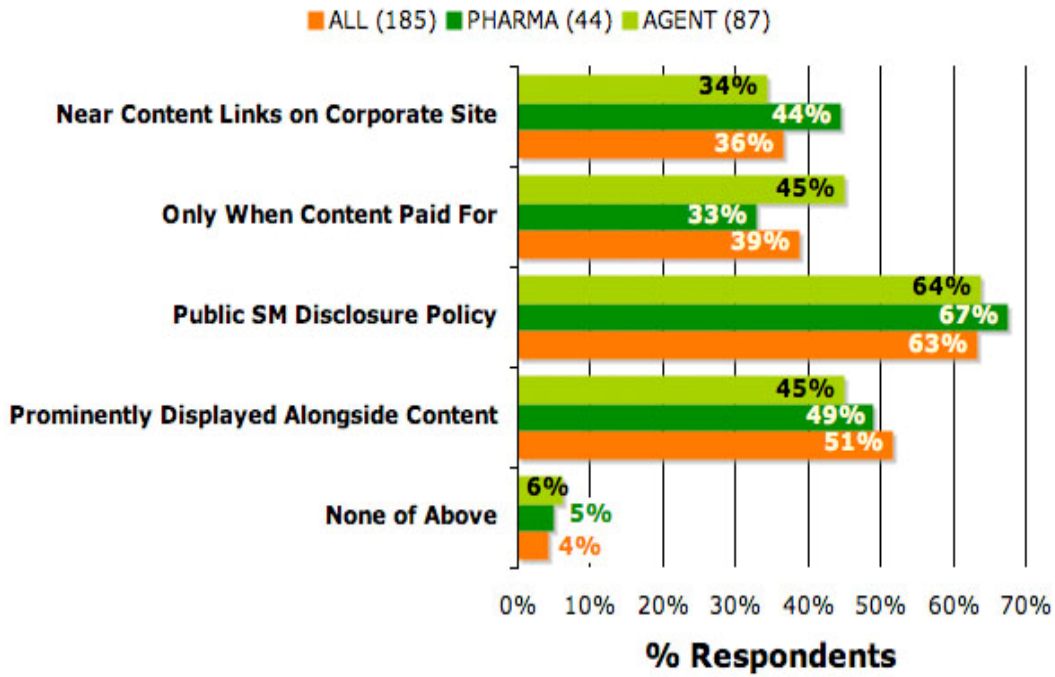
* See slide #7

Disclosure of 3rd-Party Content Involvement

Accountability

How should companies disclose their involvement or influence over discussions or material, particularly discussions or material on third-party sites?

- **Disclosure is necessary only when content is paid for**
- **Disclosure should be prominently displayed alongside relevant content when possible**
- **Disclosure and disclaimers should be included prominently on the corporate website near any links to social media outlets**
- **Each company should have a public SM policy that includes a notice of its transparency policies**

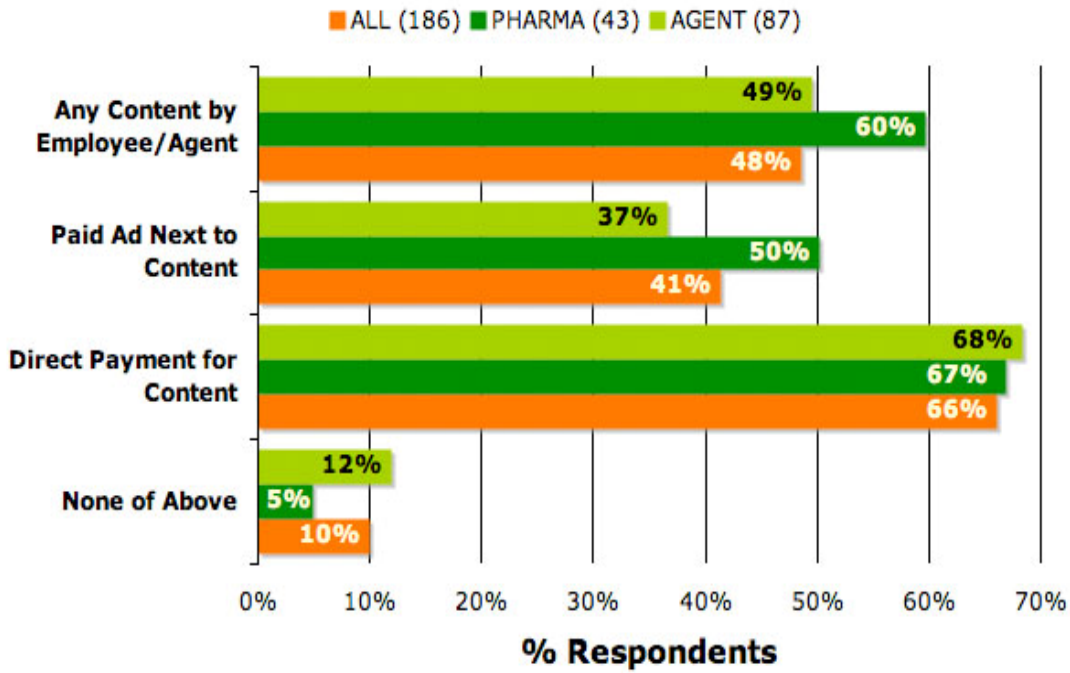


Influence Over 3rd-Party Content

Accountability

What parameters or criteria should be applied to determine when third-party communications occurring on the Internet and through social media technologies are subject to substantive influence by companies that market products related to the communication or discussion?

- **Marketer or agent paid for an ad on the page that is displayed based on the content of the page (eg, Google Adword on content sites)**
- **Marketer or agent paid for the content (eg, paid blogger or Tweeter to write about product)**
- **Any communication by anyone that is employed by, or is a consultant of, the manufacturer should be held accountable**



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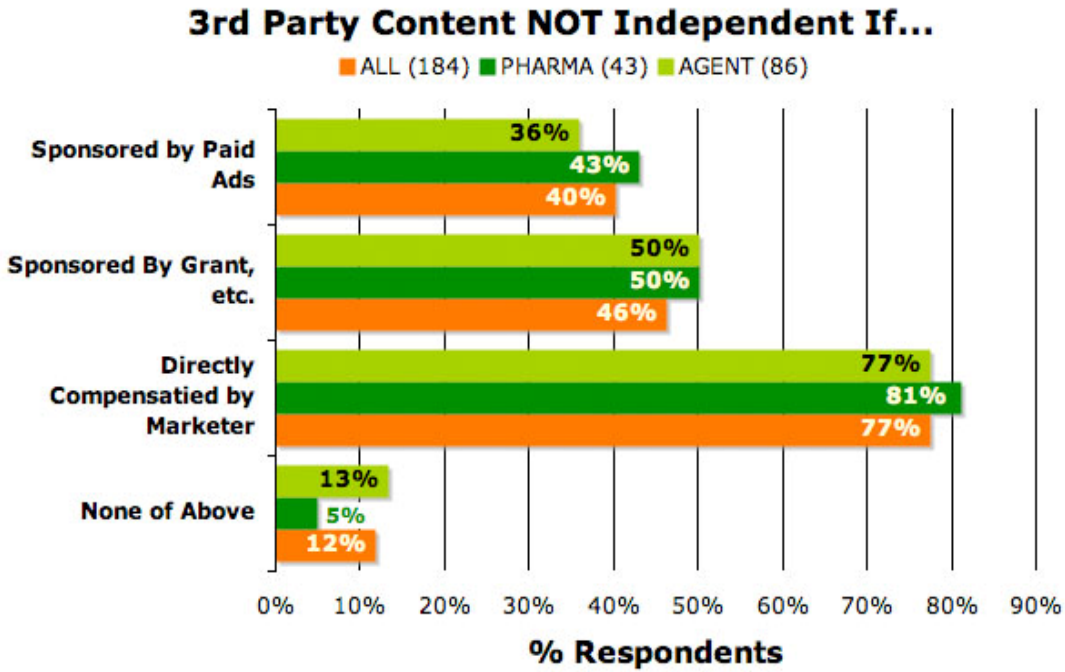
Independence of 3rd-Party Content

Accountability

When should third-party discussions be treated as being performed by, or on behalf of, the companies that market the product, as opposed to being performed independent of the influence of the companies marketing the products?

When marketer or agent

- **sponsors the discussion (eg, provides a specific grant to independent 3rd-party host such as a patient advocacy group to sponsor the discussion)**
- **paid for the content (eg, paid patients for testimonials or otherwise provided compensation)**
- **paid for display ads to be run on specific discussion pages (eg, only discussions related to the product advertised)**



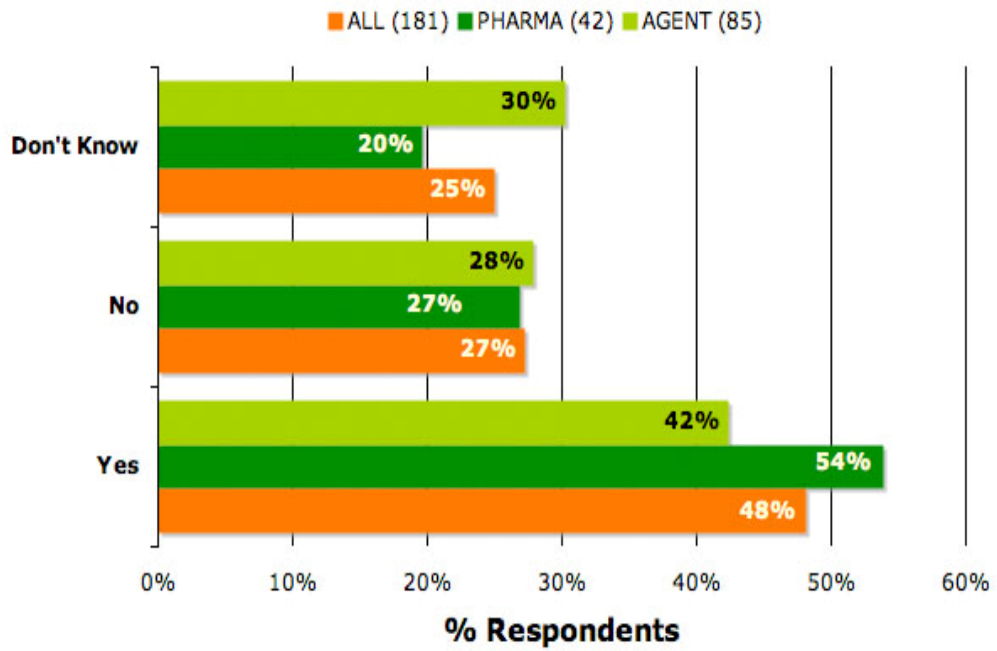
Special Media/Audience Considerations?

Accountability

Are there different considerations that should be weighed depending on the specific social media platform that is used or based on the intended audience? If so, what are these considerations?

Some considerations:

- **Space limitations (eg, Twitter vs. YouTube)**
- **Patients vs HCPs**
- **Marketing vs Disease awareness**
- **UGC vs Pharma-generated content**
- **Children vs Adults**



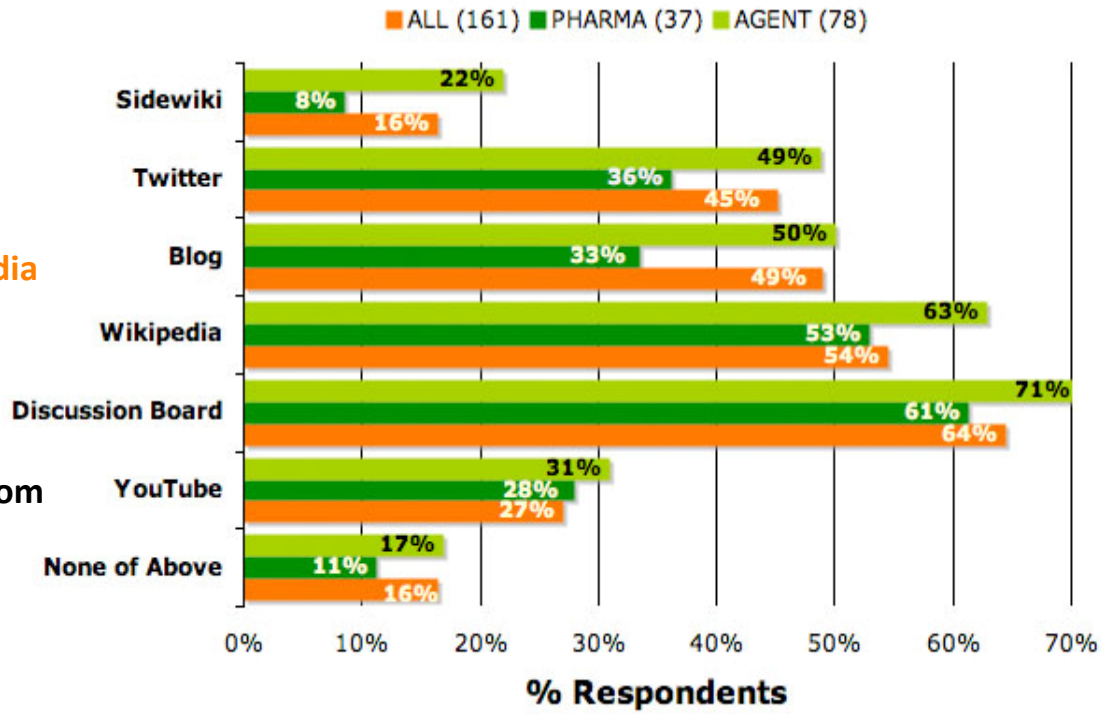
SM Sites Seen with Unauthorized Content

Accountability

With regard to the potential for company communications to be altered by third parties, what is the experience to date with respect to the unauthorized dissemination of modified product information (originally created by a company) by noncompany users of the Internet?

Unauthorized…

- product information on YouTube
- product information pages in Wikipedia
- product Twitter accounts
- Product Blogs
- communications in discussion boards
- Google Sidewiki comments on drug.com sites



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Fair Balance: Key Learnings

- Media agnostic regulations are not popular among industry experts*.
- The "One-Click Rule" is desired by the industry*. However, most often it takes two clicks to reach the approved labeling (PI). Since the PI is virtually unreadable, there needs to be a better way to provide the fair balance regardless of the number of clicks!
- There are some ideas for dealing with space limitations imposed by certain social media apps**.
  - Use of hash tags in Tweets, for example.

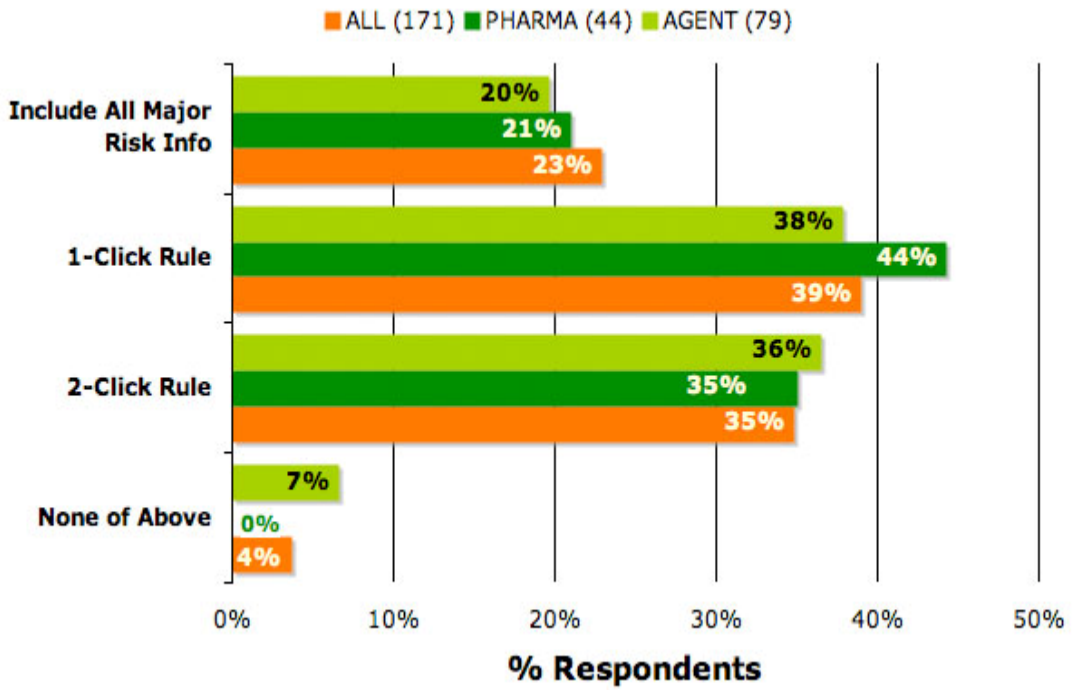
*See slide #13, **See slide #14

How to Reference Risk Information

Regulatory Requirements

How should product information be presented using various social media tools to ensure that the user has access to a balanced presentation of both risks and benefits of medical products?

- **No matter the media, all product ads should include major risk information along with benefits (media agnostic)**
- **When it is not possible to include major risk information due to space limitations, it is sufficient to include a link to the product Web site where consumers can then find all the necessary risk information in the package insert (2-click rule)**
- **When it is not possible to include major risk information due to space limitations, it is sufficient to include a link directly to the package insert (1-click rule)**

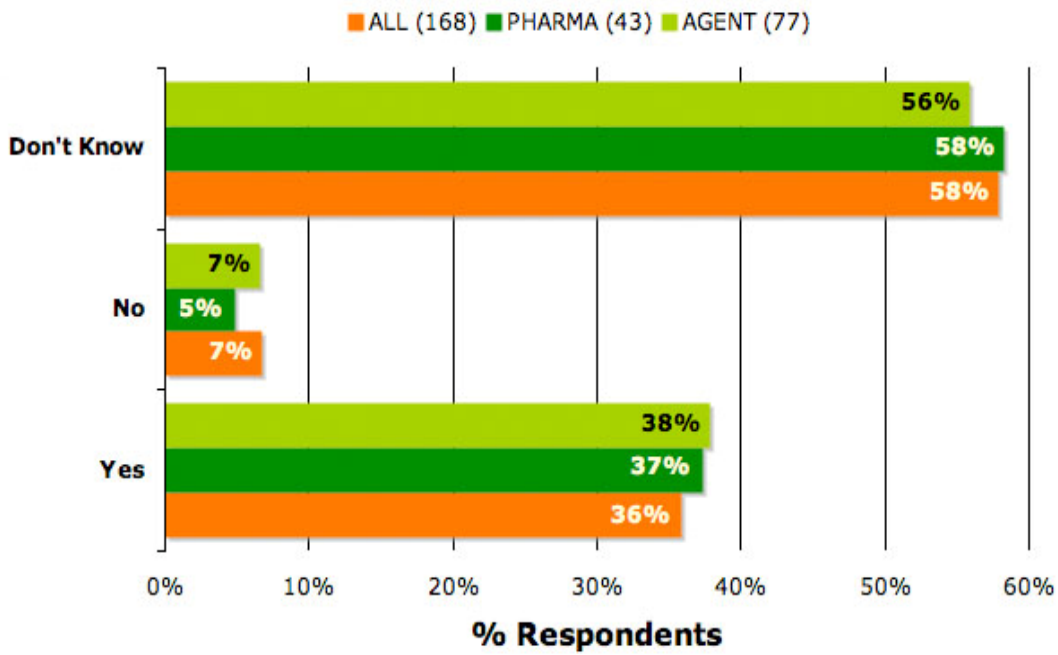


Are There Solutions for Space Limitations?

Regulatory Requirements

Are there proposed solutions that may help address regulatory concerns when using social media tools associated with space limitations or tools that allow for real-time communications to present product information?

- **"A 1-click link to the PI or the AE's in the PI is more than sufficient, we are not a nanny state! Give people the right information and let them process it."**
- **"products can be assigned hashtags by FDA, for a Twitter example (eg #Chillax), and be required to use that hashtag in all Twitter communications related to that product, so that FDA can easily review the public tweets. Not sure how the DMs would be monitored. Similar rules for other specific SM sites"**

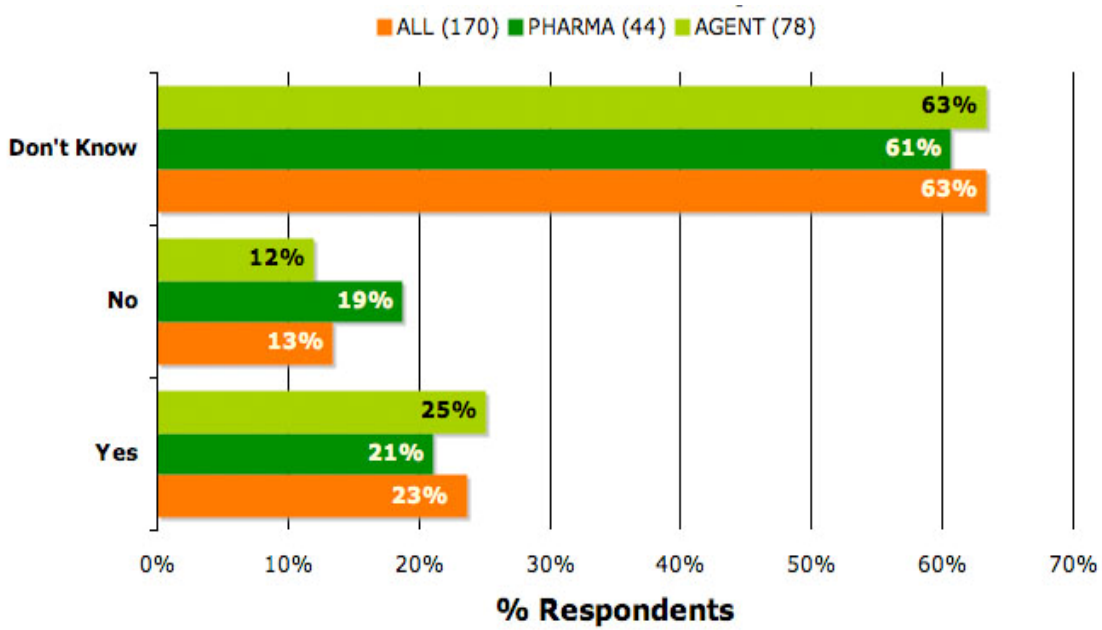


Does Presentation Format Impact Health?

Regulatory Requirements

Are there data to support conclusions about whether different types or formats of presentations have a positive or negative impact on the public health?

- **"After extensive research about social media, I have not come across any data to confirm the impact of social media on public health"**
- **"Word of mouth (ie, communities) have impact over public perception, compared to clearly labeled advertisements"**
- **"26% of purchase decisions being made through social media (Comscore)"**
- **"The power of social media has been shown to influence positive lifestyle behavior modification around smoking cessation"**



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Regulatory Requirements: Key Learnings

- Some innovative ideas for fulfilling regulatory requirements to submit social media promotional materials to FDA were suggested*, including:
  - Register sites with FDA for agency to monitor
  - Submit "template" (design and/or sample content) of social media site to FDA for pre-approval/approval
- But there was no consensus opinion about satisfying regulations regarding submission of social media promotional materials.
- Too stringent regulations will prevent companies from carrying on two-way social media conversations with consumers and HCPs. Such conversations can have a beneficial impact on public health, especially when clarifying or correcting misinformation.

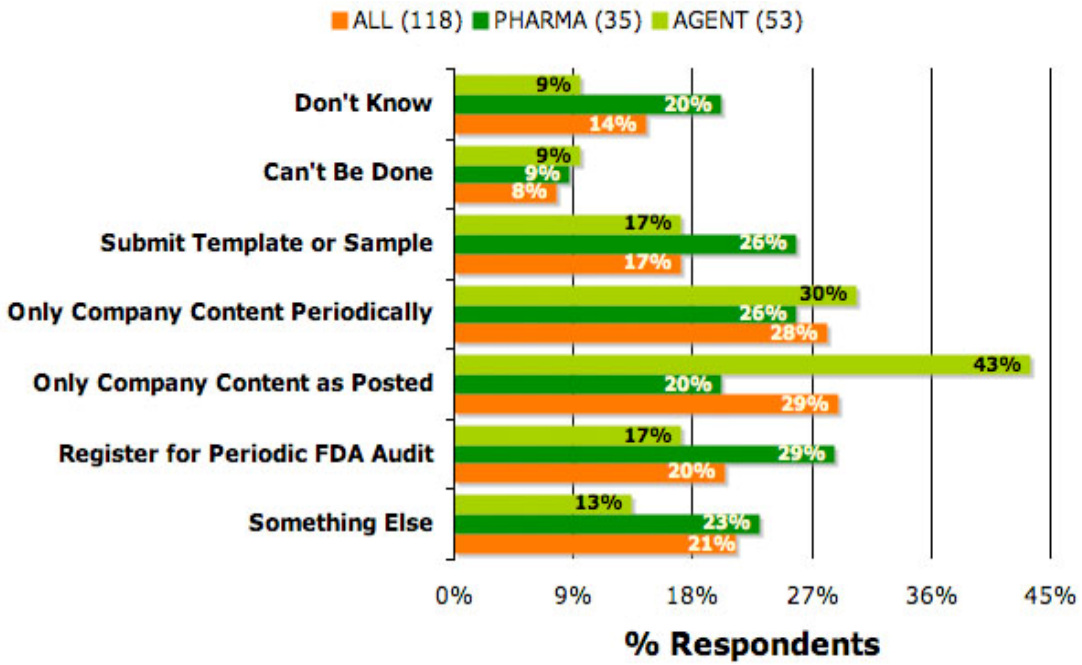
*See slide #17

How to Submit SM Content for FDA Approval

Regulatory Requirements

How should companies address the potential volume of information shared on various social media sites with regard to real-time information that is continuously posted and regulatory requirements to submit promotional materials to FDA as applicable?

- **FDA Should Audit Social Media sites on regular basis -- eg, yearly (requires mandatory registration of sites with FDA)**
- **Drug company should submit only content that it is responsible for (ie, created directly or paid a 3rd party to create) as soon as that content is posted (no submission of non-company content)**
- **Drug company should submit only content that that it creates (ie, created directly or paid a 3rd party to create) upon first use of social media site, then periodic -- eg, monthly -- submissions afterward (no submission of non-company content)**
- **Submit Social Media Site 'template' (design and/or sample content) to FDA for pre-approval/approval.**



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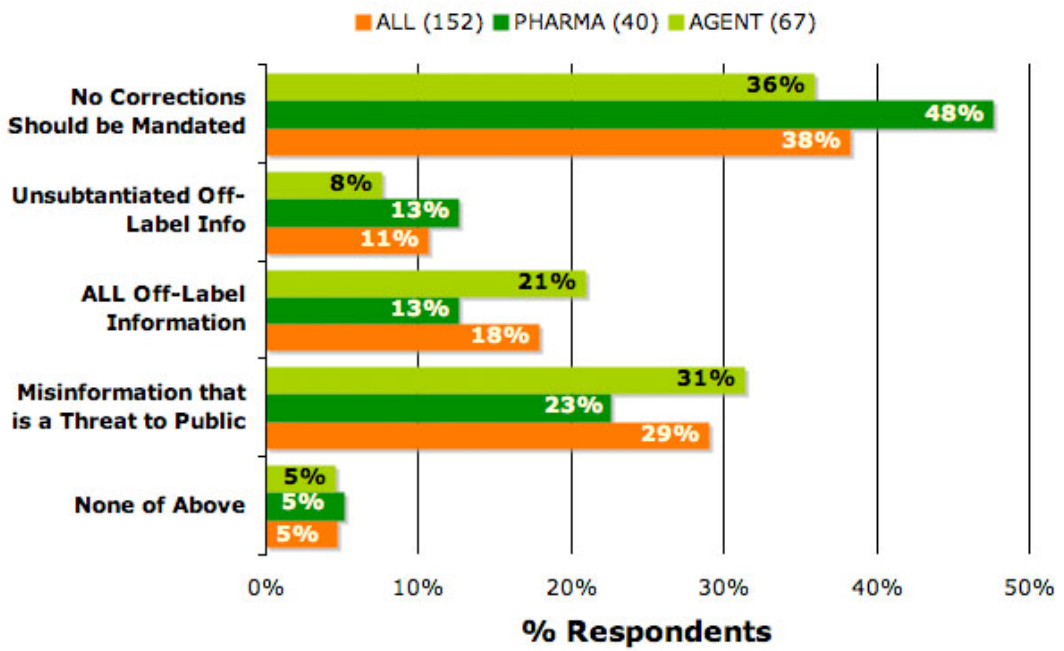
Parameters for Correcting Misinformation

Posting Corrective Information

Are there any parameters or criteria that could be used to determine the appropriateness of correcting misinformation and/or scope of information a company can provide when trying to correct misinformation on a Web site outside a company's control?

- **ONLY misinformation of real and imminent danger to the public health (to be determined by company) should be corrected**
- **ALL off-label claims—even if supported by peer-reviewed medical literature—should be corrected)**
- **Only off-label claims NOT substantiated by peer-reviewed medical literature should be corrected)**
- **Companies should not be burdened by FDA regulations requiring them to make corrections about ANY product misinformation published on third-party sites**



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Contact Information

John Mack

Follow me on Twitter:
http://twitter.com/pharmaguy

Facebook page:
http://www.facebook.com/pharmaguy

www.news.pharma-mkting.com
www.pharmamkting.blogspot.com

johnmack@virsci.com

215-504-4164
215-504-5739 (Fax)